

SUBOXONE FILM

Buprenorphine (as hydrochloride) 8mg / Naloxone (as hydrochloride) 2mg

Buprenorphine (as hydrochloride) 2mg / Naloxone (as hydrochloride) 0.5mg

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What Suboxone is used for

This medicine contains buprenorphine which belongs to a class of medicines called opioids.

This medicine has been prescribed to you and should not be given to anyone else. Opioids can cause addiction and you may get withdrawal symptoms if you stop taking it suddenly. Your doctor should have explained how long you will be taking it for, when it is appropriate to stop, and how to do this safely.

How Suboxone works

Suboxone is used to treat dependence to opioid (narcotic) drugs such as heroin or morphine in patients who have agreed to be treated for their addiction.

Suboxone is used in adults and adolescents over 15 years of age, who are also receiving medical, social, and psychological support.

Before you use Suboxone

- When you must not use it

- if you are **allergic to buprenorphine, naloxone** or any of the other ingredients of this medicine.
- if you have **serious breathing problems**.
- if you have **serious problems with your liver**.
- if you are **intoxicated due to alcohol** or have trembling, sweating, anxiety, confusion, or hallucinations caused by alcohol or other medicines that have a depressant effect on the CNS.

- Before you start to use it

Talk to your doctor, pharmacist, or nurse before using Suboxone if you have:

- seizures, fits or convulsions.
- asthma or other breathing problems

- problems with your liver such as hepatitis
- low blood pressure
- recently suffered a head injury or brain disease
- a urinary disorder (especially linked to enlarged prostate in men)
- any kidney disease
- thyroid problems
- adrenocortical disorder (e.g. Addison's disease)
- depression or other conditions that are treated with antidepressants. The use of these medicines together with Suboxone can lead to serotonin syndrome, a potentially life-threatening condition.

Suboxone contains maltitol solution, sunset yellow FCF and sodium citrate.

Suboxone contains **maltitol solution**. If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before taking this medicine.

Suboxone contains **sunset yellow FCF**, which may cause allergic reactions.

This medicine contains less than 1 mmol **sodium** (23 mg) per film, that is to say essentially 'sodium-free'.

- Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop. This is because Suboxone can affect the way some other medicines work. Also, some medicines can affect the way Suboxone works.

Some medicines may increase the side effects of Suboxone, and these can be serious. Do not take any other medicines whilst taking Suboxone without first talking to your doctor, especially:

- Benzodiazepines (used to treat anxiety or sleep disorders)
- Other opioid containing medicines such as methadone, certain painkillers and cough suppressants.
- **Antidepressants** (used to treat depression)
- **Sedating Antihistamines** (used to treat allergic reactions)
- Sedatives and alcohol.

- Clonidine (used to treat high blood pressure)
- Antiretrovirals (used to treat HIV) such as ritonavir, nelfinavir, indinavir.
- Some antifungal agents (used to treat fungal infections) such as ketoconazole, itraconazole, certain antibiotics.
- Carbamazepine, phenobarbital and phenytoin (used to treat epilepsy)
- rifampicin (used to treat tuberculosis)
- Naltrexone (medicine used to treat addictive disorders)

How to use Suboxone

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Your treatment is prescribed and monitored by doctors who are experienced in the treatment of drug dependence.

How to remove the film from the sachet

Each Suboxone film comes in a sealed child-resistant sachet. Do not open the sachet until you are ready to use it.

To open the sachet, find the dotted line that runs along the top edge of the sachet and fold the edge of the sachet along the dotted line (see Figure 1).



Figure 1

Folding the sachet along the dotted line exposes a slit through the folded edge of the sachet that can then be torn in the direction of the arrow.

Alternatively, the sachet may be cut with scissors along the arrow (see Figure 2)

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Figure 2

If the sachet is damaged, discard the film.

How to place a film under your tongue (sublingual use):

Drink water to moisten your mouth first. This helps the film dissolve more easily. Then, hold a film between two fingers by the outside edges, and place the film under your tongue, close to the base either to the left or right (see Figure 3).



Figure 3

If your doctor tells you to take two films at a time, place the second film under your tongue on the opposite side. Ensure the films do not overlap.

If your doctor tells you to take a third film, place it under your tongue on either side after the first two films have dissolved.

How to place a film on the inside of your cheek (buccal use):

Drink water to moisten your mouth.



Figure 4

Hold the film between two fingers by the outside edges and place one film on the inside of your right or left cheek (see Figure 4).

If your doctor tells you to take two

films at a time, place the other film on the inside of the opposite cheek; and this will ensure that the films do not overlap. If your doctor tells you to take a third film, place it on the inside of your right or left cheek after the first two films have dissolved.

- How much to use

Your doctor will determine the best dose for you. During your treatment, the doctor may adjust the dose, depending upon your response to treatment.

Your prescriber should discuss your treatment and whether you need to continue taking films at regular intervals. If you and your prescriber decide to stop treatment, a plan will be put in place to gradually reduce the dose and stop taking the medicine to minimize the risk of withdrawal effects.

Do not change your dose unless your doctor has told you to.

- When to use it

Take the dose once a day, at approximately the same time.

- How long to use it

Continue taking Suboxone for as long as your doctor recommends.

- If you forget to use it

Take the missed dose as soon as you remember. If it is almost time for the next dose, skip the missed dose and take only the next regularly scheduled dose. Tell your doctor as soon as possible if you miss a dose.

Do not use a double dose to make up for a forgotten dose.

- If you use too much (overdose)

Seek urgent medical attention if you or someone else takes too much of this medicine. Overdose with Suboxone may cause serious and life-threatening breathing problems.

Symptoms of overdose may include feeling sleepy and uncoordinated with slowed reflexes, blurred vision, and/or slurred speech. You may be unable to think clearly and may breathe much slower than is normal for you.

While you are using Suboxone

- Things you must do

Tell all the doctors, dentists, pharmacists and nurses treating you that you are taking SUBOXONE.

Tell your doctor immediately if you become pregnant while taking this medication.

- Things you must not do

Do not have alcohol whilst being treated with this medicine. Alcohol may increase drowsiness and may increase the risk of respiratory failure if taken with Suboxone.

Do not chew or swallow the film, as the medicine will not work, and you may get withdrawal symptoms.

Do not consume any food or drink until the film has completely dissolved.

Do not split the film or subdivide into smaller doses.

Do not take any new medicines without consulting your doctor.

Do not give SUBOXONE to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

Some people have died from respiratory failure (inability to breathe) because they misused buprenorphine or have taken it in combination with other central nervous system depressants, such as alcohol, benzodiazepines (tranquilizers), or other opioids.

This preparation may be habit forming on prolonged use.

~~Taking this medicine regularly, particularly for a long time, can lead to addiction.~~

Do not suddenly stop taking this medicine. If you want to stop taking this medicine, discuss this with your prescriber first. They will tell you how to do this, usually by reducing the dose gradually so that any unpleasant withdrawal effects are kept to a minimum. Withdrawal symptoms such as restlessness, difficulty sleeping, irritability, agitation,

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anxiety, feeling your heartbeat (palpitations), increased blood pressure, feeling or being sick, diarrhoea, shaking, shivering or sweating may occur if you suddenly stop taking this medicine.

Pregnancy and breast-feeding

Tell your doctor if you are pregnant, think you may be pregnant or are planning to have a baby. The risks of using Suboxone in pregnant women are not known.

Do not take Suboxone if you are pregnant or think you might be pregnant unless you have discussed this with your prescriber and the benefits of treatment are considered to outweigh the potential harm to the baby. Your doctor will decide if your treatment should be continued with an alternative medicine.

If you use Suboxone during pregnancy, your baby may become dependent and experience withdrawal symptoms including problems with breathing after the birth which may need to be treated. This may appear several days after birth.

Do not take Suboxone while you are breastfeeding as buprenorphine passes into breast milk and will affect your baby.

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

Suboxone may cause drowsiness, dizziness or impair your thinking.

The medicine can affect your ability to drive as it may make you sleepy or dizzy.

Talk to your doctor for further information.

Side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. Visit your doctor or pharmacist immediately if you experience any side effects after taking this medicine.

Very common (may affect more than 1 in 10 people)

- Insomnia (inability to sleep)
- constipation
- nausea
- excessive sweating
- headache
- drug withdrawal syndrome.

Common (may affect up to 1 in 10 people)

- Weight loss
- swelling of the hands and feet,
- drowsiness
- anxiety
- nervousness
- tingling, depression,
- decreased sexual drive
- abnormal liver function

Uncommon (may affect up to 1 in 100 people)

- Swollen glands (lymph nodes)
- agitation
- tremor
- abnormal dreams
- excessive muscle activity

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website npra.moh.gov.my [Public → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of Suboxone

- Storage

Keep this medicine out of the sight and reach of children.

Store below 30°C.

Do not use this medicine after the expiry date which is stated on the carton and the pouch after the expiration date.

- Disposal

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

Product Description

- What it looks like

Each SUBOXONE FILM 2MG/0.5MG is an orange rectangular soluble film imprinted with "N2" in white ink.

Each SUBOXONE FILM 8MG/2MG is an orange rectangular soluble film imprinted with "N8" in white ink.

The films are packed in individual sachets.

Pack sizes: cartons containing 28 × 1 films.

- Ingredients

- Active ingredient:

The active substance are buprenorphine and naloxone.

- Each SUBOXONE FILM 2MG/0.5MG contains 2 mg buprenorphine (as hydrochloride) and 0.5 mg naloxone (as hydrochloride dihydrate).
- Each SUBOXONE FILM 8MG/2MG contains 8 mg buprenorphine (as hydrochloride) and 2 mg naloxone (as hydrochloride dihydrate).

- Inactive ingredients

The other ingredients are maltitol solution, natural lime flavour, hypromellose, citric acid, acesulfame potassium, sodium citrate, polyethylene oxide, sunset yellow FCF and white ink.

- MAL number

First Source Licenses:

SUBOXONE FILM 2MG/0.5MG
MAL13075057ACRZ

SUBOXONE FILM 8MG/2MG
MAL13075058ACRZ

Manufacturer

Aquestive Therapeutics, Inc.
6560 Melton Road,
Portage, Indiana 46368, USA

Second Source Licenses:

Suboxone Film 2mg/0.5mg –
MAL23026005ACRSZ

Suboxone Film 8mg/2mg –
MAL23026006ACRSZ

Manufacturer

Aquestive Therapeutics, Inc.
6465 Ameriplex Drive,
Portage, Indiana, 46368, USA

Product Registration Holder

Zuellig Pharma Sdn Bhd
No. 15 Persiaran Pasak Bumi,
Seksyen U8, Perindustrian Bukit
Jelutong, 40150 Shah Alam,

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Selangor, Malaysia

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Serial Number

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